

PET



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Dated: July 28, 2005

Signature:

(Sharon Bizakas)Docket No.: 57734(11259)
(PATENT)**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
Lawrence G. Lum et al.

Application No.: 10/520,431

Group Art Unit: N/A

Filed: January 5, 2005

Examiner: Not Yet Assigned

For: TARGETING AND TRACKING OF CELLS
TO SPECIFIC ORGANS AND TISSUES IN
VIVO

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

1. Written Opinion (3 pages).

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 57734(11259). A duplicate copy of this paper is enclosed.

Dated: July 28, 2005

Respectfully submitted,

By
Kathryn A. Piffat, Ph.D.

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DEC/KAP/MLT 57734W (11259)

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo:
ROBERT L. BUCHANAN
EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

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APR 19 2005

EDWARDS & ANGELL, LLP
INDEXING DEPT. (BOS)

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing
(day/month/year)

14 APR 2005

REPLY DUE

within 1 months/days from
the above date of mailing

Applicant's or agent's file reference

57734-PCT

International application No.

PCT/US03/21142

International filing date (day/month/year)

03 July 2003 (03.07.2003)

Priority date (day/month/year)

05 July 2002 (05.07.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 39/395; A01N 63/00; A61K 35/26, 35/28 and US Cl.: 424/136.1, 153.1, 155.1, 93.7, 577

Applicant

ROGER WILLIAMS MEDICAL CENTER

- This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
 - ☒ Basis of the opinion
 - ☐ Priority
 - ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Lack of unity of invention
 - ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Certain documents cited
 - ☐ Certain defects in the international application
 - ☐ Certain observations on the international application
- The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

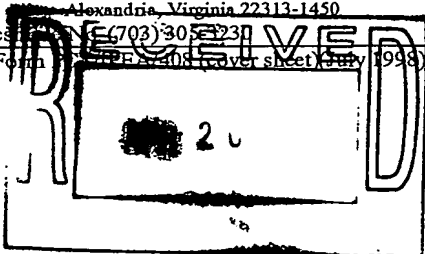
If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 05 November 2004 (05.11.2004).

Name and mailing address of the IPEA/US
Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Authorized officer

Michail A. Belyavsky

Telephone No. 571-272-1600

Facsimile No. (703) 305-1230
Form PCT/US 03 (cover sheet) (July 1998)

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written opinion
Edwards & Angell LLP

101 Federal St. Boston, MA 02110

Cocketed For 4/30/05-5/14/05
By me

Approved _____

WRITTEN OPINION

International application No.

PCT/US03/21142

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages 1-67, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the claims:
pages 68-75, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the drawings:
pages NONE, as originally filed
pages 1-9, filed with the demand
pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE _____
- ☒ the claims, Nos. NONE _____
- ☒ the drawings, sheets/fig NONE _____

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

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WRITTEN OPINION

International application No.
PCT/US03/21142

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-14 and 26-54</u>	YES
	Claims <u>15-25</u>	NO
Inventive Step (IS)	Claims <u>1-14</u>	YES
	Claims <u>15-54</u>	NO
Industrial Applicability (IA)	Claims <u>1-54</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 15-25 lack novelty under PCT Article 33(2) as being anticipated by SEN et al.

SEN et al., teach a method of treating a patient suffering from cancer comprising isolating peripheral blood mononuclear cells from a patient suffering from cancer, activating T cells by ex-vivo stimulating with anti-CD3 monoclonal antibody and arming activated T cells with bispecific antibodies binding the secondary labeled antibody specific for the FC region of the bispecific antibody and reinfusing the armed and labeled activated T cell into the patient (see entire document, Material and Method, pages 257, and 258 in particular).

The reference teaching anticipated the claimed invention.

Claims 26-54 lack an inventive step under PCT Article 33(3) as being obvious over Sen et al.

The teaching of Sen et al. have being discussed supra.

SEN et al., do not teach a method for tracking cells in vivo at any desired location. However, said functional properties would be an obvious variation of the method taught by SEN et al.

Claims 1-14 meet the criteria set out in PCT Article 33(2) and (3), because the prior art does not teach or fairly suggest the claimed invention as recited in claims 1-14.

Claims 1-54 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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WRITTEN OPINION

International application No.
PCT/US03/21142

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

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